OPTN Kidney & Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
August 26, 2022
Conference Call

Asif Sharfuddin, MD, Chair

Introduction

The Kidney & Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via Citrix GoTo teleconference on 08/26/2022 to discuss the following agenda items:

1. Welcome
2. Overview of Kidney and Pancreas Continuous Distribution Project
3. Review Boards
4. Closing Remarks

The following is a summary of the Workgroup's discussions.

1. Welcome

The Chair welcomed the Workgroup members to the meeting. The Workgroup members introduced themselves and their experience in transplant.

Staff provided a brief overview of the Workgroup's purpose and scope.

The Workgroup has been tasked with establishing review boards for kidney and pancreas transplantation and identifying exceptions that can be requested within the continuous distribution framework. The Workgroup will also provide operational guidance for the review boards.

The Workgroup will make recommendations for establishing kidney and pancreas review boards that then must be approved by the OPTN Kidney Transplantation Committee and the OPTN Pancreas Transplantation Committee. The approved recommendations will be incorporated into the main continuous distribution proposal which is slated for August 2023 for public comment.

Summary of discussion:

There was no discussion.

2. Overview of Kidney and Pancreas Continuous Distribution Project

Staff provided an overview of continuous distribution, its history, and the plan moving forward.

Presentation Summary:

Background and Overview

In 2018, the OPTN Board of Directors selected continuous distribution as the allocation framework for all organs that would incorporate the most effective pieces from the current allocation process for each organ. Moving all organs to the same basic allocation framework will make it easier for patients and transplant professionals to understand the allocation process and any changes made to that process, while also allowing for more objective conversations regarding the allocation of organs. The purpose of the continuous distribution framework was to be broad enough to ensure consistency across organs, but

also flexible enough to allow for clinical and values differences for each organ type. Lung was the first organ allocation system to transition to continuous distribution, and kidney and pancreas will be the second organs to simultaneously transition to continuous distribution.

Continuous distribution will create a composite allocation score (CAS) based on five different goals: medical urgency, transplant outcomes, candidate biology, patient access, placement efficiency.

The kidney and pancreas continuous distribution project is currently in the "modeling and analysis" phase of development. Many of the attributes for kidney and pancreas are currently in policy, and the community has suggested other attributes they want to see either added into continuous distribution or addressed in the future. An analytical hierarchy process (AHP) exercise, which was used to inform the weight of each attribute, went out for public comment in January 2022 and the results were incorporated in the Strategic Registry of Transplant Recipients (SRTR) modeling request. Once the results of the modeling request are received, changes may need to be made to the weights of the attributes and further modeling may need to be done.

Attributes

Staff shared the attributes sent to the SRTR for modeling:

- Medical Urgency
    - Kidney: Medical Urgency Definition
- Transplant Outcomes:
    - Kidney: DR Matching, Longevity
- Candidate Biology
    - Kidney: Blood type, Calculated Panel Reactive Antibody (CPRA)
    - Pancreas, kidney-pancreas (KP), and Islets: Blood type identical, CPRA
- Patient Access:
    - Kidney: Pediatrics, Prior Living Donors, Waiting Time, Kidneys After Liver (KAL) safety net
    - Pancreas, KP, and Islets: Pediatrics, Prior Living Donors, Waiting Time
- Placement Efficiency:
    - Kidney: Proximity Efficiency (distance to transplant hospital)
    - Pancreas, KP, and Islets: Organ registration, proximity efficiency

Rating Scales and Weights

Staff explained the distinction between an attribute's weight and rating scale. The weights are values related decisions; for example, how important is medical urgency versus (vs.) patient access vs. placement efficiency. The rating scales are derived from clinical and operational data. Staff reviewed the pancreas and kidney rating scales that were sent to the SRTR for modeling.

Weight Modifiers

Current kidney allocation differs depending on the kidney donor profile index (KDPI) of the donor kidney. To replicate this, the OPTN Kidney Committee is incorporating donor weight modifiers depending on donor factors. These weight modifiers are included in the Kidney-Pancreas Simulated Allocation Model (KPSAM) and serve to replicate priority in existing KDPI sequences for kidney. Similarly, the OPTN Pancreas Committee will be incorporating weight modifiers for donor factors specific to pancreas, namely donor age and body mass index (BMI). It is of note that these weight modifiers prioritize whole pancreas candidates for donors aged 45 and younger with a BMI of 30 and under, and prioritize islet candidates for donors over the age of 45 or a BMI over 30.

Progress So Far

A modeling request has been submitted to the SRTR. There is currently an updated paper out for public comment, which includes an in-depth discussion of the AHP results, modeling request, and other considerations outside the CAS. These considerations include dual kidney, en bloc, facilitated pancreas, mandatory KP offers, national offers, screening and filters, released organs, and review boards. Review boards are critical for considering edge cases, and under continuous distribution all organs will have review boards which allows for consistency in conversations about these cases.

Summary of discussion:

A Workgroup member asked if the impact of multiorgan transplants has been considered. Staff stated that multiorgan transplant has been under consideration since the beginning of continuous distribution planning, and eventually continuous distribution will include multiorgan match runs. However, the first step is to establish continuous distribution for each organ. Staff mentioned that there is a group creating a road map to achieve continuous distribution for multiorgan transplant.

A Workgroup member asked if there has been any discussion on the relationship between the different factors that were presented (i.e., pediatric recipients and prior living donors, and how those would interact with KDPI and medical urgency). Staff responded that the determination was made to favor simplicity and transparency over some of the interactions. Currently the score is mostly additive although there is still the capability of allowing interaction within the scale. There may be a change made in the future, but for initial implementation the scoring system will remain the same.

3. Review Boards

Staff provided a summary of the general purpose of review boards and how they will operate within the kidney and pancreas continuous distribution framework.

Currently review boards quickly review specific, urgent-status patient registrations on the OPTN heart, liver, and lung transplant waitlist. Review board members collectively determine whether these listings are appropriate, based entirely on clinical information that complies with OPTN policies.

There are operational guidelines that instruct members and staff about the confidential medical peer review process. The guidelines specify requirements for review board members, initial review and appeal process steps, process time frame, and possible outcomes.

There is also clinical guidance, these are not official guidelines for clinical practice, nor are they intended to be clinically prescriptive or to define a standard of care. These resources are intended to provide guidance to transplant programs and review boards. As an example, the heart review board considers adult congenital heart disease (CHD) exceptions.

Currently, neither kidney nor pancreas have review boards, but with the transition to continuous distribution each organ system will establish a review board. This Workgroup will identify candidate-based attributes that transplant centers can request as exceptions for kidney and pancreas. A framework has been established to ensure consistency for review boards across organs and the Workgroup will review the framework to ensure that the structure clinically suits kidney and pancreas.

Summary of discussion:

There was no discussion.

4. Closing Remarks

During the next Workgroup meeting, the way in which the continuous distribution review board framework will work will be discussed. Additionally, members from the OPTN Lung Transplantation

Committee will discuss with the Workgroup their experience with transitioning review boards to lung continuous distribution. The purpose of the next meeting is to get the Workgroup acquainted with the framework of continuous distribution.

Summary of discussion:

Staff asked if the current day and time of the meeting works for everyone or if another option would work better. A Workgroup member said that they would prefer mid-morning meetings on Tuesday or Thursday.

Upcoming Meeting

- September 09, 2022

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Dean Kim
  - Maria Helena Friday
  - Michael Marvin
  - Namrata Jain
  - Stephen Almont
  - Reem Raafat
  - Todd Pesavento
- **UNOS Staff**
  - Alex Carmack
  - James Alcorn
  - Jennifer Musick
  - Kayla Temple
  - Keighly Bradbrook
  - Kim Uccellini
  - Krissy Laurie
  - Lauren Motley
  - Lindsay Larkin
  - Ross Walton
  - Sarah Booker
  - Rebecca Brookman